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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/071,349	02/06/2002	Dani P. Bolognesi	7872-087	3907
20583	7590	03/24/2004	EXAMINER	
JONES DAY 222 EAST 41ST STREET NEW YORK, NY 10017			PARKIN, JEFFREY S	
			ART UNIT	PAPER NUMBER
			1648	

DATE MAILED: 03/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/071,349

Applicant(s)

BOLOGNESI ET AL.

Examiner

Jeffrey S. Parkin, Ph.D.

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 03 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 and 48 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 and 48 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 11202003.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

Serial No.: 10/071,349
Applicants: Bolognesi, D. P., et al.

Docket No.: 7872-087
Filing Date: 02/06/02

Detailed Office Action

Status of the Claims

Applicants' election without traverse of Group I (claims 1-13) in the response filed 11 December, 2003, is acknowledged. Claims 14-47 were canceled without prejudice or disclaimer and new claim 48 submitted. Claims 1-13 and 48 are pending in the instant application.

37 C.F.R. § 1.98

The information disclosure statement filed 20 November, 2003, has been placed in the application file and the information referred to therein has been considered.

35 U.S.C. § 112, Second Paragraph

Claim 48 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The recited methodology steps are confusing and ambiguous. It is not readily manifest at what point in the assay the contact step and measuring steps are to be performed. Appropriate correction is required.

35 U.S.C. § 103(a)

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter

sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. § 103(c) and potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103(a).

Claims 1-13 and 48 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Brinchmann *et al.* (1990) in view of Connor *et al.* (1995) and Jackson *et al.* (1998).

Brinchmann *et al.* (1990) describe the inhibitory effect exerted by activated CD8⁺ T cells on the replication of HIV in naturally infected CD4⁺ T cells. Highly purified CD4⁺ T cells from asymptomatic HIV seropositive individuals were stimulated with anti-TCR mAb-coated beads in the presence of IL-2. HIV was subsequently reproducibly isolated in cell supernatants from all study participants (53 cultures from 42 individuals). Both autologous and allogeneic CD8⁺ T cells from asymptomatic HIV seropositive and healthy HIV seronegative individuals inhibited

the replication of HIV in these cultures in a dose-dependent manner. CD8⁺ T cells from patients with AIDS showed reduced or no such inhibitory activity. The inhibitory effect was not dependent on direct cell-cell contact: an inhibitory effect was exerted by CD8⁺ T cells across a semipermeable membrane, and an inhibitory activity was also exerted by the cell-free supernatants from activated CD8⁺ T cells. These results demonstrate that activated CD8⁺ T cells secrete a soluble inhibitor of HIV replication. This teaching does not disclose the utilization of a retroviral vector particle pseudotype assay to assay the stage of replication wherein viral replication is impaired.

Connor *et al.* (1995) describe a sensitive, single-cycle replicative assay employing HIV-1 pseudoparticles and a luciferase HIV-1 reporter vector. This assay system was used to demonstrate that vpr is important for efficient viral replication in primary monocyte/macrophages, but appears to play no role in activated or resting T cell infection. The block to infection in monocytes was localized by PCR analysis of newly synthesized viral DNA and with the luciferase reporter vector to a stage in the viral life cycle after entry and reverse transcription, yet prior to, or at the time of, proviral transcription. In addition, infection of mononuclear phagocytes with virions that had been loaded with Vpr molecules in the producer cells by trans-complementation still showed a vpr-phenotype. These data suggest a role for vpr molecules produced in newly infected cells, in addition to its presumed function in the virion. Thus, this system provides a rapid and facile means for identifying the stages of viral replication that any given protein functions.

Jackson *et al.* (1998) also describe a system employing HIV-1 pseudoparticles to investigate the effect of tat inhibition on

HIV replication. A retroviral vector was constructed to express an anti-tat hammerhead ribozyme as part of the 3' untranslated region of beta-galactosidase transcripts. Initial testing of this vector in tat-expressing COS-7 cells reduced tat activity by 85-95% as measured by tat-dependent CAT assays. Amphotropic and HIV-pseudotyped retroviral particles generated with this vector were used in HIV challenge experiments to determine the ability of this reagent to control HIV replication. CD4⁺ peripheral blood lymphocytes (PBLs) stably transduced with this vector were subsequently challenged with HIV. These cells were able to resist HIV infection for up to 20 days as measured by cell death and reverse transcriptase activity. These data yield proof of principle that a pseudotyped retroviral vector can target and deliver a protective ribozyme to CD4⁺ cells.

Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to utilize HIV-1 pseudotyped viral particles, as taught by Connor *et al.* (1995) and Jackson *et al.* (1998), to develop a screening assay to ascertain the activity and viral steps affected by CD8 suppressor molecules as provided by Brinchmann *et al.* (1990).

Non-statutory Double Patenting

The non-statutory double patenting rejection, whether of the obviousness-type or non-obviousness-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington*, 418 F.2d 528, 163 U.S.P.Q. 644 (C.C.P.A. 1969). *In re Vogel*, 422 F.2d 438, 164 U.S.P.Q. 619 (C.C.P.A. 1970). *In re Van Ornum*, 686 F.2d 937, 214 U.S.P.Q. 761 (C.C.P.A. 1982). *In re Longi*, 759 F.2d 887, 225 U.S.P.Q. 645

(Fed. Cir. 1985). *In re Goodman*, 29 U.S.P.Q.2d 2010 (Fed. Cir. 1993). A timely filed terminal disclaimer in compliance with 37 C.F.R. § 1.321(b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R. § 1.78(d). Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 C.F.R. § 3.73(b).

Claims 1-13 and 48 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,586,174, in view of Connor *et al.* (1995) and Jackson *et al.* (1998). Although the conflicting claims are not identical, they are not patentably distinct from each other. The teachings of Connor *et al.* (1995) and Jackson *et al.* (1998) have been discussed *supra*. Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to utilize HIV-1 pseudotyped viral particles, as taught by Connor *et al.* (1995) and Jackson *et al.* (1998), to develop a screening assay to ascertain the activity and viral steps affected by CD8 suppressor molecules as provided by the '174 patent.

Claims 1-13 and 48 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 5,861,490, in view of Connor *et al.* (1995) and Jackson *et al.* (1998). Although the conflicting claims are not identical, they are not patentably distinct from each other. The teachings of Connor *et al.* (1995) and Jackson *et al.* (1998) have been discussed *supra*.

Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to utilize HIV-1 pseudotyped viral particles, as taught by Connor *et al.* (1995) and Jackson *et al.* (1998), to develop a screening assay to ascertain the activity and viral steps affected by CD8 suppressor molecules as provided by the '490 patent.

Claims 1-13 and 48 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Patent No. 5,627,023, in view of Connor *et al.* (1995) and Jackson *et al.* (1998). Although the conflicting claims are not identical, they are not patentably distinct from each other. The teachings of Connor *et al.* (1995) and Jackson *et al.* (1998) have been discussed *supra*. Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to utilize HIV-1 pseudotyped viral particles, as taught by Connor *et al.* (1995) and Jackson *et al.* (1998), to develop a screening assay to ascertain the activity and viral steps affected by CD8 suppressor molecules as provided by the '023 patent.

Correspondence

Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (571) 272-0908. The examiner can normally be reached Monday through Thursday from 9:30 AM to 7:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisors, Laurie Scheiner or James Housel, can be reached at (571) 272-0910 or (571) 272-0902, respectively. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (571) 272-1600.

Respectfully,

A handwritten signature in black ink, appearing to read 'Jeffrey S. Parkin', with a large, stylized initial 'J'.

Jeffrey S. Parkin, Ph.D.
Patent Examiner
Art Unit 1648

21 March, 2004